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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,971	03/11/2004	Rudolf Zihlmann	34126/US	5343
25763	7590	11/22/2006		
DORSEY & WHITNEY LLP INTELLECTUAL PROPERTY DEPARTMENT SUITE 1500 50 SOUTH SIXTH STREET MINNEAPOLIS, MN 55402-1498				
			EXAMINER MIGGINS, MICHAEL C	
			ART UNIT 1772	PAPER NUMBER
DATE MAILED: 11/22/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/798,971

Applicant(s)

ZIHLMANN, RUDOLF

Examiner

Michael C. Miggins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/6/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 6-7 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilfong et al. (US 5407713).

Wilfong discloses a multi-layered plastic body for storing or conducting a medical, diagnostic pharmaceutical or/and cosmetic product (Fig. 1, abstract, column 37, lines 10-25), said plastic body comprising a first layer made of a stress fracture resistant plastic material (14 from Fig. 1 and column 17, line 5 through column 18, line 20), and at least a second layer, connected to said first layer, and made of a plastic material which exhibits a lower resistance to stress fractures than said first plastic material (16 from Fig. 1 and column 17, line 5 through column 18, line 20) (applies to instant claim 1).

Wilfong discloses wherein the first layer forms an outer layer of the plastic body, thereby forming a skin (Fig. 1 and column 37, lines 10-25), wherein the plastic material of the second layer a lower permeability than the stress fraction layer (since the second layer is more permeable to moisture than the moisture resistant outer layer), wherein the second layer is arranged between the first layer and another layer made of one of the same or another stress fracture resistant plastic material (Fig. 1), wherein the first layer is connected to the second layer through a material and/or positive lock (since

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layers 14 from Fig. 1 are in direct contact with layer 12 from Fig. 1) (applies to instant claims 6-7 and 10-13).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilfong et al. (US 5407713) in view of Cooke (US 5371124).

Wilfong fails to disclose wherein the stress fracture resistant plastic material is semi-crystalline which has a crystalline portion of at least 30%. However, Wilfong does disclose that the stress fracture resistant material of the outer layers is radiation resistant polypropylene (14 from Fig. 1 and column 17, line 5 through column 18, line 20, column 11, lines 10-40).

Cooke discloses a semi-crystalline polypropylene with improved radiation resistant properties in medical articles which has a crystalline portion of at least 30% (abstract, column 2, lines 3-41, column 4, lines 28-38).

Therefore it would have been obvious to one of ordinary skill in the art at the time applicant's invention was made to have provided the semi-crystalline polypropylene material which has a crystalline portion of at least 30% in the outer layer of Wilfong in order to provide improved radiation resistance as taught or suggested by Cooke.

5. Claims 2-5 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilfong et al. (US 5407713) in view of Mathur et al. (US 6178832).

Wilfong discloses tublings (column 37, lines 10-25), wherein at least the first layer encloses a hollow space formed by the plastic body (Fig. 1 and column 37, lines 10-25) (applies to instant claim 3).

Wilfong fails to disclose wherein the plastic body is at least part of a container, the container being one of a group comprising ampoules, catheters or components of a fluid handling system, wherein the plastic body comprises at least one opening sealed by a septum and wherein the septum is cast in.

Mathur discloses wherein the plastic body is at least part of a container, the container being one of a group comprising ampoules, catheters or components of a fluid handling system, wherein the plastic body comprises at least one opening sealed by a septum and wherein the septum is cast in (Figs. 9a-9c and column 24, line 30 through column 25, line 58) (applies to instant claims 2-5) for the purpose of preventing fluid/reagent loss from the pouch or entry of contaminants into the pouch.

Therefore it would have been obvious to one of ordinary skill in the art at the time applicant's invention was made to have provided wherein the plastic body is at least part of a container, the container being one of a group comprising ampoules, catheters or components of a fluid handling system, wherein the plastic body comprises at least one opening sealed by a septum and wherein the septum is cast-in in the pouch of

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Wilfong in order to prevent fluid/reagent loss from the pouch or entry of contaminants into the pouch as taught or suggested by Mathur.

Claims 14-17 recite method limitations such as "injection molding" etc. which have little patentable weight since the method by which a part is formed adds no structural limitations to the product claims (MPEP 2113) and thus the prior does not need to disclose applicant's method limitations to read on the claims as written.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Miggins whose telephone number is 571-272-1494. The examiner can normally be reached on 1:00-10:00pm.

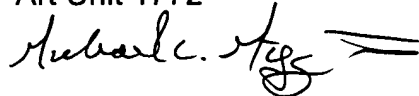
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Y. Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCM  
November 13, 2006

Michael C. Miggins  
Primary Examiner  
Art Unit 1772

A handwritten signature in black ink, appearing to read "Michael C. Miggins", followed by a horizontal line and a checkmark-like flourish.